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Alphatec Spine

510(k) SUMMARY
September 2010

Submitter: Alphatec Spine, Inc.
5818 El Camino Real
Carlsbad, CA 92008
Direct: (760) 494-6739
Fax: (760) 431-0289

Official Contact: Olga Lewis, Regulatory Affairs Specialist

Trade/Model Name: BridgePoint™ Spinous Process Clamp-
Posterior Fixation System

Common Name: Spinal Intervertebral Body Fixation Orthosis

Classification Regulation: KWP - Spinal Interlaminal Fixation Orthosis

Device Description:

The BridgePoint™ Spinous Process Clamp- Posterior Fixation System is an implantable device that clamps bilaterally to the spinous processes. It is a multi-component device consisting of two sets of plates. Each set is composed of a male and female plate. Two sets are coupled by two rigid posts that connect and pivot at the midline. The plates have a male and female component which slide and result in a variable plate length. These sliding plates are locked by a lateral set screw.

Indications for Use

The BridgePoint™ Spinous Process Clamp System is a posterior, non-pedicle supplemental fixation device, intended for use in non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. It is not intended for stand alone use.

Substantial Equivalence:

The BridgePoint™ Spinous Process Clamp System is substantially equivalent in intended use and function to NuVasive® Spinous Process Plate System (k073278)

BridgePoint™ Spinous Process Clamp- Posterior Fixation System

Alphatec Spine

Technological Characteristics Comparison:

The BridgePoint™ Spinous Process Clamp System is substantially equivalent to the referenced device in that it is intended to be used for plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in non-cervical spine (T1-S1).

Material composition is identical to numerous other Alphatec Spine products that have been cleared via the 510(k) process.

Nonclinical Performance Data:

Mechanical testing for BridgePoint™ Spinous Process Clamp- Posterior Fixation System was performed that provides reasonable assurance of safety and effectiveness for device's intended use. Performance testing was performed per the recognized consensus standards and per the guidance document, *Spinal System 510(k)s - Guidance for Industry and FDA Staff*. This testing documented both static and fatigue performance characteristics. This testing clearly demonstrated that the performance characteristics satisfy the requirements of posterior non-pedicle supplemental fixation. As a result of this testing, the BridgePoint™ Spinous Process Clamp System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Alphatec Spine, Inc.
% Ms. Olga Lewis
Regulatory Affairs Specialist
5818 El Camino Real
Carlsbad, California 92008

Re: K103205
Trade Name: BridgePoint Spinous Process Clamp - Posterior Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: May 09, 2011
Received: May 10, 2011

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Mark N. Melkerson per D.R.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103205

Device Name: BridgePoint™ Spinous Process Clamp – Posterior Fixation System

Indications For Use:

The BridgePoint™ Spinous Process Clamp System is a posterior, non-pedicle supplemental fixation device, intended for use in non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. It is not intended for stand alone use.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103205